

PATENT COOPERATION TREATY

DOCKETED

NML

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:
ALICE O. CARROLL
HAMILTON, BROOK, SMITH & REYNOLDS, P.C
530 VIRGINIA ROAD
PO BOX 9133
CONCORD, MA 01742-9133

PCT

WRITTEN OPINION

(PCT Rule 66)

Applicant's or agent's file reference		Date of Mailing (day/month/year)
3593.1001001		7.23.04
REPLY DUE		within 1 months/days from the above date of mailing
International application No.	International filing date (day/month/year)	Priority date (day/month/year)
PCT/US03/27975	04 September 2003 (04.09.2003)	04 September 2002 (04.09.2002)
International Patent Classification (IPC) or both national classification and IPC		
IPC(7): A61K 31/715, 39/395 and US Cl.: 424/155.1; 514/54		
Applicant		FOREIGN DOCKETING
UNIVERSITY OF LOUISVILLE RESEARCH FOUNDATION, INC		

- Completed By _____
1. This written opinion is the first (first, etc.) drawn by this International Preliminary Examining Authority.
2. This opinion contains indications relating to the following items:
- I ☒ Basis of the opinion
 - II ☐ Priority
 - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
 - IV ☐ Lack of unity of invention
 - V ☒ Reasoned statement under Rule 66.2 (a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
 - VI ☐ Certain documents cited
 - VII ☐ Certain defects in the international application
 - VIII ☐ Certain observations on the international application

3. The applicant is hereby invited to reply to this opinion.

When? See the time limit indicated above. ~~The applicant may, before the expiration of that time limit, request this Authority to grant an extension. See rule 66.2(d).~~

How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

Also For an additional opportunity to submit amendments, see Rule 66.4.
For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4 bis.
For an informal communication with the examiner, see Rule 66.6

If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.

4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is: 04 January 2005 (04.01.2005)

Name and mailing address of the IPEA/US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 873-9306	Authorized officer <i>Valerie Red-Harris</i> Rebecca Cook Telephone No. 571/272-1600
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Form PCT/IPEA/408 (cover sheet)(July 1998)

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WRITTEN OPINION

(PCT Rule 66)

Date of Mailing (day/month/year) 23 JUL 2004	
Applicant's or agent's file reference 3593.1001001	REPLY DUE within 1 months/days from the above date of mailing
International application No. PCT/US03/27975	International filing date (day/month/year) 04 September 2003 (04.09.2003)
Priority date (day/month/year) 04 September 2002 (04.09.2002)	
International Patent Classification (IPC) or both national classification and IPC IPC(7): A61K 31/715, 39/395 and US Cl.: 424/155.1; 514/54	
Applicant UNIVERSITY OF LOUISVILLE RESEARCH FOUNDATION, INC	

1. This written opinion is the <u>first</u> (first, etc.) drawn by this International Preliminary Examining Authority.	
2. This opinion contains indications relating to the following items: <ul style="list-style-type: none"> I <input checked="" type="checkbox"/> Basis of the opinion II <input type="checkbox"/> Priority III <input type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability IV <input type="checkbox"/> Lack of unity of invention V <input checked="" type="checkbox"/> Reasoned statement under Rule 66.2 (a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement VI <input type="checkbox"/> Certain documents cited VII <input type="checkbox"/> Certain defects in the international application VIII <input type="checkbox"/> Certain observations on the international application 	
3. The applicant is hereby invited to reply to this opinion. <p>When? See the time limit indicated above. The applicant may, before the expiration of that time limit, request this Authority to grant an extension. See rule 66.2(d).</p> <p>How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.</p> <p>Also For an additional opportunity to submit amendments, see Rule 66.4. For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4 bis. For an informal communication with the examiner, see Rule 66.6</p> <p>If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.</p>	
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WRITTEN OPINION

International application No.

PCT/US03/27975

I. Basis of the opinion

1. With regard to the elements of the international application:*

- ☒ the international application as originally filed
- ☒ the description:
 pages 1-62, as originally filed
 pages NONE, filed with the demand
 pages NONE, filed with the letter of _____
- ☒ the claims:
 pages 63-65, as originally filed
 pages NONE, as amended (together with any statement) under Article 19
 pages NONE, filed with the demand
 pages NONE, filed with the letter of _____
- ☒ the drawings:
 pages 1-26, as originally filed
 pages NONE, filed with the demand
 pages NONE, filed with the letter of _____
- ☐ the sequence listing part of the description:
 pages NONE, as originally filed
 pages NONE, filed with the demand
 pages NONE, filed with the letter of _____

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language _____ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the written opinion was drawn on the basis of the sequence listing:

- ☐ contained in the international application in printed form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☒ The amendments have resulted in the cancellation of:

- ☒ the description, pages none
- ☒ the claims, Nos. none
- ☒ the drawings, sheets/fig none

5. ☐ This opinion has been drawn as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed."

WRITTEN OPINION

International application No.
PCT/US03/27975

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. STATEMENT

Novelty (N)	Claims <u>NONE</u>	YES
	Claims <u>1-2, 5-13, 15</u>	NO
Inventive Step (IS)	Claims <u>NONE</u>	YES
	Claims <u>1-15</u>	NO
Industrial Applicability (IA)	Claims <u>1-15</u>	YES
	Claims <u>NONE</u>	NO

2. CITATIONS AND EXPLANATIONS

Claims 1-2, 5-13, 15 lack novelty under PCT Article 33(2) as being anticipated by HCAPLUS DN 137:119657. HCAPLUS DN 137:119657 teaches a method of treating neoplastic disease using a glucan and an anti-tumor antibody.

Claims 3-4 and 14 lack inventive step under PCT Article 33(3) as being obvious over HCAPLUS DN 137:119657 in view of Wang et al and MEDLINE AN 2000285552. HCAPLUS DN 137:119657 teaches a method of treating neoplastic disease using a glucan and an anti-tumor antibody. The claims differ over HCAPLUS DN 137:119657 in reciting a specific antibody, conformation of neutral soluble glucan and route of administration. However, Wang discloses that use of the specifically recited monoclonal antibodies are accepted clinical practice in patients with neoplastic disease. Additionally, MEDLINE AN 2000285552 discloses that soluble glucans exist in the recited conformations. Moreover, once a method of using a compound is known it is within the skill of the artisan to determine the optimum route of administration.

Claims 1-15 meet the criteria set out in PCT Article 33(4), and thus find industrial applicability because the subject matter claimed can be made or used in industry.

----- NEW CITATIONS -----

Wang, S. C. et al, Targeting HER2: recent developments and future directions for breast cancer patients, Semin. Oncol., 28:21-29, 2001, see abstract.

WRITTEN OPINION

International application No.
PCT/US03/27975

Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

TIME LIMIT:

The time limit set for response to a Written Opinion may not be extended. 37 CFR 1.484(d). Any response received after the expiration of the time limit set in the Written Opinion will not be considered in preparing the International Preliminary Examination Report.